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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,575	01/09/2001	Joerg Kaufmann	59516-216(pp-01656.002	9437
7590	10/17/2008			
Chiron Corporation			EXAMINER	
Intellectual Property R338			HARRIS, ALANA M	
P.O. Box 8097				
Emeryville, CA 94662-8097			ART UNIT	PAPER NUMBER
			1643	
			MAIL DATE	DELIVERY MODE
			10/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/758,575	Applicant(s) KAUFMANN ET AL.
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

- 1) Responsive to communication(s) filed on 23 June 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,5-11 and 36-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 1 and 6-11 is/are allowed.
- 6) Claim(s) 5 and 36-49 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Response to Amendments and Arguments

1. Claims 1, 5-11, 36-39, 41-47 and 49 are pending.
Claims 40 and 48 have been cancelled.
Claims 5, 36 and 49 have been amended.
Claims 1, 5-11, 36-39, 41-47 and 49 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

3. The rejection of claims 5, 36-39, 41-47 and 49 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of amendments to the claims. Claims 40 and 48 have been cancelled.

4. The rejection of claim 49 under 35 U.S.C. 112, second paragraph, presented in section b. of the rejection set forth on page 6 of the former Action mailed February 21, 2008 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of amendment to claim 49. Claim 48 has been cancelled.

Maintained and New Grounds of Rejections

Claim Rejections - 35 USC § 112

5. The rejection of claim 47 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is made and maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.** Claim 48 has been cancelled.

Applicants point out pertinent passages of the specification that allegedly support the context of claim 47 which is regarded by the Examiner as new matter. It seems these noted sections read on hybridization probes and method of implementing the claimed nucleic acid molecules. These teachings are not commensurate in scope to claimed subject matter. These arguments and points of view have been carefully considered, but found unpersuasive.

These arguments do not obviate the instant rejection. Applicants are reminded claim 47 depend from three independent claims, which read on the isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide; a polynucleotide at least 95% identical to a polynucleotide; and a polynucleotide encoding

These arguments do not obviate the instant rejection. Applicants are reminded claim 47 depends from three independent claims, which read on the isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide; a

polynucleotide at least 95% identical to a polynucleotide; and a polynucleotide encoding a polypeptide at least 95% identical to SEQ ID NO: 2 wherein the nucleic acid molecule comprises nucleotides 365-1173 of SEQ ID NO: 1. The Examiner does not note support for the fragments of SEQ ID NO: 1 encoding a polypeptide (amino acids 1 to 273; amino acids 2 to 273; nor 26 to 273 of SEQ ID NO: 2); the fragments of SEQ ID NO: 1 encoding a polypeptide at least 95% identical to SEQ ID NO: 2. The fragment listed in claim 47 recited in the specification, page 22 and page 23, respectively. However, it remains the context of these recitations do not overlap with the claimed invention. In essence, these passages within the specification do not support the breadth of the claims. Applicants should delete the new matter or point out proper and in-context support for claim 47.

6. Claims 5, 36-39, 41-47 and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants broadly claim an isolated nucleic acid molecule that is at least 95%-98% identical to polynucleotides encoding amino acids; and an isolated nucleic acid molecule comprising polynucleotide encoding a polypeptide with no more than 5 conservative amino acid substitutions;

wherein the amino acids/polypeptide has the amino acid sequence selected from the group consisting of:

1 to 273 of SEQ ID NO: 2;

2 to 273 of SEQ ID NO: 2; and

26 to 273 of SEQ ID NO: 2. The said polynucleotide is contained in vector and host cell and produced utilizing art known recombinant technology. The specification while being enabling for the nucleic acid identified as SEQ ID NO: 1 which encodes the amino acid sequence, SEQ ID NO: 2, does not reasonably provide enablement for variants that have at least 95% sequence identity to polynucleotides that encode SEQ ID NO: 2. Furthermore, nucleic acids that encode polypeptides with substitutions placed inside a vector and consequently a host cell would not encode a protein or the protein of SEQ ID NO: 2. There is no guidance as to how to use these divergent sequences or how to use these sequences.

The encoded products of these at least 95% sequence identical nucleic acids may possess function that is not commensurate with the functions of the native protein. The nucleic acids will encode proteins that may not maintain the activities proposed in the specification, such as a marker for distinguishing between tumors, which will or have metastasized. Likewise, it would seem that specific function(s) would be required to make the encoded protein useful for the applications disclosed in the specification and the claims. Since the amino acid sequence of a polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar activity requires a knowledge

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of and guidance with regard to which amino acid or acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved and detailed knowledge of the ways in which the protein's structure relates to its function. The specification provides essentially no guidance as to which of the infinite possible choices is likely to be successful especially in selection of at least one conservative amino acid substitution within the range of *about 1 to about 273 amino acid residues of SEQ ID NO: 2* (see claim 5). The true fact of the state of the art in peptide chemistry is expressed succinctly in the Lazar article (Molecular and Cellular Biology 8(3): 1247-1252, March 1988) mailed November 18, 2004. This article presents data that substantiates the fact that the introduction of mutations in an amino acid sequence will yield products with different biological activity from the wild type protein.

From the discussion above, it is clear that the predictability of changes to the nucleic acid sequence and its forthcoming amino acid sequence is practically nil as far as biological activities are concerned. Moreover, a sequence(s) that encodes a protein with substitutions is more than likely to result in expression of polypeptide inconsistent with SEQ ID NO: 2. The specification fails to provide sufficient guidance to enable one of ordinary skill in the art to make and use the claimed nucleic acids in a manner reasonably correlated with the broad scope of the claims. Without such guidance, the changes which must be made in the nucleic acid sequence of SEQ ID NO: 1, which results in nucleic acid sequences with 95% identity is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive

and undue. See *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016 and *Ex parte Forman*, 230 USPQ 546 (BPAI 1986).

7. The rejection of claim 47 under 35 U.S.C. 112, second paragraph, presented in section a. of the rejection set forth on page 6 of the former Action mailed February 21, 2008 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

Applicants assert the dependency of the claim is not intended to suggest that nucleic acid fragment (446 to 1173 of SEQ ID NO: 1) encodes the recited amino acids, see Remarks submitted June 23, 2008, page 10, first paragraph. Applicants attempt to further arguments by presenting claim 47 as an independent claim including limitations of claim 5 asserting the nucleic acid fragment is not intended to encode the portions of SEQ ID NO: 2 listed in claim 5. These arguments have been carefully reviewed, as well as reconsidered, but found unpersuasive.

As set forth in the rewritten claim listed in the Remarks cited the rewritten claim reads on a isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide that has the three different sets of amino acids of SEQ ID NO: 2. The isolated nucleic acid molecule is 446 to 1173 of SEQ ID NO: 1. This fully implies that this specific nucleotide sequence encodes a particular amino acid sequence. The rewritten claim submits to that this and clearly establishes that. The rejection is maintained for the reasons of record and set forth herein.

Allowable Subject Matter

8. Claims 1 and 7-11 are allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.

14 October 2008

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643

Application Number 	Application/Control No.	Applicant(s)/Patent under Reexamination
	09/758,575 Examiner Alana M. Harris, Ph.D.	KAUFMANN ET AL. Art Unit 1643